

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D0940535	(X3) Date Survey Completed 09/20/2022
Name of Provider or Supplier Frederic Clinic	Street Address, City, State 205 W Oak St, Frederic, WI	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2005	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p> <p>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of Certification and Surveyor Provider Enhanced Reporting (CASPER) records and American Proficiency Institute (API) forms, and interview with the laboratory director, the laboratory did not report proficiency test results to Health and Human Services (HHS) or Centers for Medicare and Medicaid Services (CMS) for the prothrombin time / international normalized ratio (PT/INR) regulated analyte in 2020, 2021, and 2022. Findings include: 1. Review of the CASPER report 0155D (Individual Laboratory Profile) for the laboratory on September 15, 2022 showed no proficiency testing data available for the PT/INR regulated analyte for events 1 through 3 in 2020 and 2021 and events one and two in 2022. 2. Review of the API "Comparative Evaluation Report" form showed the PT INR test is not marked as an analyte that is scored for CMS. 3. Interview with the laboratory director at 9:30 AM, confirmed the laboratory did not report proficiency test results to CMS for the PT /INR regulated analyte in 2020, 2021, or 2022.</p>
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p>

This STANDARD is not met as evidenced by:
Based on surveyor review of personnel records and interview with the laboratory director, the director did not evaluate and document the competence of a technical consultant (staff A) for this laboratory in 2021 or 2022. Findings include: 1. Review of personnel records from 2021 and 2022 showed no evidence of competence evaluation for staff A as a technical consultant. 2. Interview with the laboratory director on September 20, 2022 at 9:15 AM confirmed the director did not evaluate the competence of technical consultant staff A at this laboratory in 2021 or 2022.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on surveyor review of laboratory procedures and records and interview with the laboratory director, the laboratory did not perform calibration verification of the i-STAT Troponin and BNP (B-type natriuretic peptide) tests every six months in 2021 or 2022. Findings include: 1. Review of the "i-STAT BNPs, Troponins, Chem 8+ Creat and PT/INRs" procedure showed, "Cal ver will be done on BNP and troponin once every 6 months". 2. Review of laboratory records showed no evidence of calibration verification for BNP and Troponin tests in 2021 and 2022. 3. Interview with the laboratory director on September 20, 2022 at 11:15 AM confirmed the laboratory did not perform calibration verification every six months for the BNP or Troponin tests as required by the laboratory procedures.